

Notice of Allowability

Application No.

09/856,576

Examiner

Christopher J Nichols, Ph.D.

Applicant(s)

ERIKSSON, PETER

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 21 April 2004.
2. ☒ The allowed claim(s) is/are 53,59 and 62-72.
3. ☒ The drawings filed on 10 October 2003 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Response and Amendment filed 21 April 2004 has been received and entered in full.
2. Pursuant to MPEP 706.07(e), the finality of the previous Office Action (21 November 2003) is hereby *withdrawn* and prosecution on the merits reopened.

Withdrawn Objections And/Or Rejections

3. The Declaration under 37 CFR 1.132 filed 21 April 2004 is sufficient to overcome the rejection of claims **53, 59, and 62-72** under 35 U.S.C. §112 ¶1 as set forth at pp. 4-5 ¶¶10-16 in the previous Office Action (21 November 2003).
4. In view of the Declaration and acceptance of the below Examiner's Amendment, all Objections and Rejections previously set forth are hereby *withdrawn*.

EXAMINER'S AMENDMENT

5. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

In the Claims:

Claims 1-52 (Cancelled)

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Claim 53 (Previously Presented) A method of Claim 59, wherein the growth hormone is further administered to said brain cells during *in vitro* propagation.

Claims 54-58 (Cancelled)

Claim 59 (Currently Amended) A method of propagating cells selected from the group consisting of neuronal progenitor cells and neuronal stem cells in, or derived from, the central or peripheral nervous system in a mammalian patient in need of neuron propagation comprising:

- (A) administering a composition comprising a pharmaceutically effective amount of a mammalian growth hormone to said patient, wherein said pharmaceutically effective amount is effective to propagate neuronal progenitor cells and neuronal stem cells;
- (B) removing brain cell from said patient;
- (C) propagating said brain cell *in vitro*; and
- (D) transplanting the propagated brain cells into said patient.

Claims 60-61 (Cancelled)

Claim 62 (Previously Presented) A method of Claim 59, wherein the growth hormone comprising composition is administered by intravenous peripheral infusion or by intramuscular or subcutaneous injection.

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Claim 63 (Previously Presented) A method of Claim 62, wherein the growth hormone comprising composition is administered by subcutaneous injection.

Claim 64 (Previously Presented) A method of Claim 62, wherein the growth hormone comprising composition is administered in a dosage of from about 0.01 to about 1IU/kg body weight of the patient per week.

Claim 65 (Currently Amended) A method of any one of Claims 59, 62, 63, or 64, wherein the composition comprises a further compound or composition capable of inducing cell genesis or proliferation is administered ~~in step a) of Claim 59~~ to said cells prior to removal from said patient.

Claim 66 (Currently Amended) A method of Claim 65, wherein the further compound or composition are selected from the group consisting of peptides, growth factors, steroids, lipids, glycosylated proteins, and ~~peptides or~~ combinations thereof.

Claim 67 (Previously Presented) A method of Claim 66, wherein the further compound is a growth factor.

Claim 69 (Previously Presented) A method of Claim 68, wherein the combination of compounds or compositions is administered simultaneously.

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Claim 70 (Previously Presented) A method of Claim 69, wherein the combination of compounds or compositions is administered sequentially.

Claim 71 (Currently Amended) A method of Claim 59, wherein the patient suffers from a condition associated with central nervous system damage or ~~deficiency~~, neuronal cell loss, ~~or memory loss~~.

Claim 72 (Currently Amended) A method of Claim 71, wherein the neuronal cell loss ~~or memory loss~~ is multiple sclerosis, hypoxic injury, ischemic injury, traumatic injury, Parkinson's disease, or a demyelination disorder.

6. Authorization for this examiner's amendment was given in a telephone interview with Mercedes Meyer (Reg. No. 44,939) on 11 May 2004.

Summary

7. Claims **53, 59, and 62-72** are hereby allowed.

8. The Examiner acknowledges that acceptance of the above Examiner's Amendment does not mitigate in any way, shape, or form, Applicant's right to pursue additional subject matter in continuation, continuation-in-part, and/or divisional applications pursuant to 35 U.S.C. §120 and §121.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on **(571) 272-0887**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN
May 12, 2004



ELIZABETH KEMMERER
PRIMARY EXAMINER